II

115TH CONGRESS
1ST SESSION

S. 1093

To amend the Federal Food, Drug, and Cosmetic Act to improve pediatric medical device application procedures.

IN THE SENATE OF THE UNITED STATES

MAY 10, 2017

Mr. FRANKEN (for himself and Mr. ENZI) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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A BILL

To amend the Federal Food, Drug, and Cosmetic Act to improve pediatric medical device application procedures.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Pediatric Device Development Act''.

SEC. 2. PEDIATRIC USES OF DEVICES.

Section 515A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e–1) is amended—

(1) in subsection (a)(3)—

(A) by redesignating subparagraphs (B) through (D) as subparagraphs (D) through (F), respectively;

(B) by inserting after subparagraph (A) the following:

''(B) an assessment of pediatric device labeling needs, based on a review of real world evidence on the off-label use of medical devices in children, drawn from data available to the Food and Drug Administration;

''(C) the number of devices that receive a humanitarian use exemption under section 520(m);'';

(C) in subparagraph (E) (as so redesignated), by striking ''; and'' and inserting '';'';

(D) in subparagraph (F) (as so redesignated), by striking ''(B), and (C).'' and inserting ''(C), (D), and (E); and''; and

(E) by adding at the end the following:

''(G) the number of devices for which extrapolation was used to support the approval of pediatric labeling of such devices.

For the items described in this paragraph, such report shall disaggregate the number of devices by pediatric subpopulation.'';

(2) by redesignating subsection (c) as subsection (d); and

(3) by inserting after subsection (b), the following:

''(c) PEDIATRIC DEVICE INNOVATION.—

''(1) IN GENERAL.—The Secretary shall, not later than 1 year after the date of enactment of the Pediatric Device Development Act, establish within the Center for Devices and Radiological Health a structure to—

''(A) provide assistance to device manufacturers, in coordination with the relevant review committees, as appropriate, that would result in the development, approval, and labeling of medical devices for children;

''(B) oversee an internal pediatrics team that—

''(i) is comprised of—

''(I) employees of the Food and Drug Administration with expertise in pediatrics and appropriate expertise pertaining to the relevant devices under review; and

''(II) other individuals designated by the Secretary; and

''(ii) provides expertise and consultation on—

''(I) the application of subsection (b), section 520(m), section 510(k), and section 522 of this Act and section 402 of the Public Health Service Act to pediatric devices; and

''(II) pediatrics, as it pertains to reviewing devices, to all applicable divisions within the Center for Devices and Radiological Health;

''(C) coordinate pediatric activities within the Center for Devices and Radiological Health; and

''(D) collaborate with other programs, offices, and centers of the Food and Drug Administration, including the consortia program authorized under section 305 of the Pediatric Medical Device Safety and Improvement Act of 2007.

''(2) STAFF.—Such structure shall include a chief pediatric medical officer and other appropriate individuals as the Secretary determines necessary.''.

SEC. 3. HUMANITARIAN DEVICE EXEMPTION.

Section 520(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(m)) is amended—

(1) in paragraph (4)—

(A) by striking ''an institutional review committee'' each place such term appears and inserting ''an institutional review board or an appropriate local committee''; and

(B) by striking ''the institutional review committee'' and inserting ''the institutional review board or the appropriate local committee''; and

(2) in paragraph (6)(A)(iv), by striking ''2017'' and inserting ''2022''.

SEC. 4. DEMONSTRATION GRANTS FOR IMPROVING PEDIATRIC AVAILABILITY.

Section 305 of the Pediatric Medical Device Safety and Improvement Act of 2007 (Public Law 110–85; 42 U.S.C. 282 note) is amended—

(1) in subsection (c)—

(A) in paragraph (4), by striking ''and'' at the end;

(B) in paragraph (5), by striking the period and inserting ''; and''; and

(C) by adding at the end the following:

''(6) providing regulatory consultation to device sponsors in support of the submission of an application for a pediatric device, where appropriate.''; and

(2) in subsection (e), by striking ''2017'' and inserting ''2022''.

SEC. 5. MEETING ON PEDIATRIC DEVICE DEVELOPMENT.

(a) IN GENERAL.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services shall convene a public meeting regarding opportunities and barriers to the development, approval, and labeling of pediatric medical devices. Such meeting shall include representatives from the medical device industry, academia, recipients of funding under section 305 of the Pediatric Medical Device Safety and Improvement Act of 2007 (Public Law 110–85; 42 U.S.C. 282 note), medical provider organizations, and organizations representing patients and consumers.

(b) TOPICS.—The meeting described in subsection (a) shall include consideration of ways to—

(1) improve research infrastructure and research networks to facilitate the conduct of clinical studies of devices for children that would result in the approval and labeling of medical devices for children;

(2) appropriately use extrapolation under section 515A(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e–1(b));

(3) enhance the appropriate use of postmarket registries and data to increase pediatric medical device labeling;

(4) increase Food and Drug Administration assistance to medical device manufacturers in developing devices for children that are approved and labeled for their use; and

(5) identify current barriers to pediatric device development and incentives to address such barriers.

(c) REPORT.—Not later than 6 months after the meeting described in subsection (a), the Secretary of Health and Human Services shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate, and publish, including on the Internet website of the Food and Drug Administration, a report that summarizes and responds to the recommendations raised in such meeting.

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